



PRIVACY IMPACT ASSESSMENT (PIA)

For the

Roche Cobas Blood Gas and Electrolyte (BGE) Analyzer and BGE Link Software
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US Army Medical Command - DHP Funded System

SECTION 1: IS A PIA REQUIRED?

a. Will this Department of Defense (DoD) information system or electronic collection of information (referred to as an "electronic collection" for the purpose of this form) collect, maintain, use, and/or disseminate PII about members of the public, Federal personnel, contractors or foreign nationals employed at U.S. military facilities internationally? Choose one option from the choices below. (Choose (3) for foreign nationals).

- ☐ (1) Yes, from members of the general public.
- ☐ (2) Yes, from Federal personnel* and/or Federal contractors.
- ☒ (3) Yes, from both members of the general public and Federal personnel and/or Federal contractors.
- ☐ (4) No

* "Federal personnel" are referred to in the DoD IT Portfolio Repository (DITPR) as "Federal employees."

b. If "No," ensure that DITPR or the authoritative database that updates DITPR is annotated for the reason(s) why a PIA is not required. If the DoD information system or electronic collection is not in DITPR, ensure that the reason(s) are recorded in appropriate documentation.

c. If "Yes," then a PIA is required. Proceed to Section 2.

SECTION 2: PIA SUMMARY INFORMATION

a. Why is this PIA being created or updated? Choose one:

- ☐ **New DoD Information System** ☐ **New Electronic Collection**
- ☒ **Existing DoD Information System** ☐ **Existing Electronic Collection**
- ☐ **Significantly Modified DoD Information System**

b. Is this DoD information system registered in the DITPR or the DoD Secret Internet Protocol Router Network (SIPRNET) IT Registry?

- ☐ **Yes, DITPR** Enter DITPR System Identification Number
- ☐ **Yes, SIPRNET** Enter SIPRNET Identification Number
- ☒ **No**

c. Does this DoD information system have an IT investment Unique Project Identifier (UPI), required by section 53 of Office of Management and Budget (OMB) Circular A-11?

- ☐ **Yes** ☒ **No**

If "Yes," enter UPI

If unsure, consult the Component IT Budget Point of Contact to obtain the UPI.

d. Does this DoD information system or electronic collection require a Privacy Act System of Records Notice (SORN)?

A Privacy Act SORN is required if the information system or electronic collection contains information about U.S. citizens or lawful permanent U.S. residents that is retrieved by name or other unique identifier. PIA and Privacy Act SORN information should be consistent.

- ☒ **Yes** ☐ **No**

If "Yes," enter Privacy Act SORN Identifier

A0040-66b DASG

DoD Component-assigned designator, not the Federal Register number.
Consult the Component Privacy Office for additional information or
access DoD Privacy Act SORNs at: <http://www.defenselink.mil/privacy/notices/>

or

Date of submission for approval to Defense Privacy Office

Consult the Component Privacy Office for this date.

e. Does this DoD information system or electronic collection have an OMB Control Number?

Contact the Component Information Management Control Officer or DoD Clearance Officer for this information.

This number indicates OMB approval to collect data from 10 or more members of the public in a 12-month period regardless of form or format.

☐ **Yes**

Enter OMB Control Number

Enter Expiration Date

☒ **No**

f. Authority to collect information. A Federal law, Executive Order of the President (EO), or DoD requirement must authorize the collection and maintenance of a system of records.

(1) If this system has a Privacy Act SORN, the authorities in this PIA and the existing Privacy Act SORN should be the same.

(2) Cite the authority for this DoD information system or electronic collection to collect, use, maintain and/or disseminate PII. (If multiple authorities are cited, provide all that apply.)

(a) Whenever possible, cite the specific provisions of the statute and/or EO that authorizes the operation of the system and the collection of PII.

(b) If a specific statute or EO does not exist, determine if an indirect statutory authority can be cited. An indirect authority may be cited if the authority requires the operation or administration of a program, the execution of which will require the collection and maintenance of a system of records.

(c) DoD Components can use their general statutory grants of authority ("internal housekeeping") as the primary authority. The requirement, directive, or instruction implementing the statute within the DoD Component should be identified.

10 U.S.C. 3013, Secretary of the Army; 10 U.S.C. 1071-1085, Medical and Dental Care; 50 U.S.C. Supplement IV, Appendix 454, as amended, Persons liable for training and service; 42 U.S.C. Chapter 117, Sections 11131-11152, Reporting of Information; 10 U.S.C. 1097a and 1097b TRICARE Prime and TRICARE Program; 10 U.S.C. 1079, Contracts for Medical Care for Spouses and Children; 10 U.S.C. 1079a, CHAMPUS; 10 U.S.C. 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents; E.O. 9397 (SSN); DoD Instruction 6015.23, Delivery of Healthcare at Military Treatment Facilities (MTFs); DoD Directive 6040.37, Confidentiality of Medical Quality Assurance (QA) Records; DoD 6010.8-R, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Army Regulation 40-66, Medical Record Administration and Health Care Documentation.

g. Summary of DoD information system or electronic collection. Answers to these questions should be consistent with security guidelines for release of information to the public.

(1) Describe the purpose of this DoD information system or electronic collection and briefly describe the types of personal information about individuals collected in the system.

Roche Cobas BGE Link (formally Omnilink) is a single point of control for the collection and management of blood gas and electrolyte data for the Cobas b 221 System . The Cobas BGE Link system provides instant access to patient demographics, orders and test results, as well as Quality Control(QC) and maintenance information. Cobas BGE Link can be customized for specific requirements. The Cobas BGE Link system is customized for multiple critical-care testing scenarios and allows seamless information integration into every Laboratory Information System(LIS) or Hospital Information System(HIS). Cobas BGE link has various connectivity options; system collects data - direct serial or direct Ethernet connectivity options - in 'real time' from test locations, including the main laboratory, near-patient testing site or at the patient's bedside. Additional features: QC data is available on one screen for a comprehensive and easy review of data by the laboratory supervisor. Cobas BGE link has an automated tracking system supports to compliant with College of American Pathologists(CAP) regulatory requirements. Cobas BGE link has the ability with system reports to cover lab requirements (patient data, QC, maintenance, productivity and more) and is customizable to individual, departmental and regulatory needs. Data and PII information is stored on the Cobas Server.

Collection of PII include name, social security number and other medical information as needed for patient care.

(2) Briefly describe the privacy risks associated with the PII collected and how these risks are addressed to safeguard privacy.

The risks associated with the collection, use, and storage of personally identifiable information (PII) and protected health information (PHI) are unauthorized access and unauthorized disclosure. Loss or compromise could occur through insecure or misdirected digital transmission, unauthorized access to or unauthorized viewing of a DoD information system, insecure storage (data-at-rest), or loss of printed copy. Appropriate safeguards are in place to minimize the these risks and the possibility of disclosure.

h. With whom will the PII be shared through data exchange, both within your DoD Component and outside your Component (e.g., other DoD Components, Federal Agencies)? Indicate all that apply .

☒ **Within the DoD Component.**

Specify.

The PII will be shared with health care providers within the medical treatment facility using this software.

☒ **Other DoD Components.**

Specify.

The PII is available to health care providers at Air Force, and Navy medical treatment facilities after the individual has signed an authorization for disclosure.

Madigan provides medical PII to providers at Joint Base Lewis (Army) and McChord Field (Air Force) medical clinics. Oak Harbor and Bremerton Naval Hospitals have patients that may receive medical treatment locally at MAMC and the results of that treatment is shared with the outside providers.

☒ **Other Federal Agencies.**

Specify. Department of Veterans Affairs (Medical & Benefits Office) and Veterans Affairs Hospitals.

☐ **State and Local Agencies.**

Specify.

☒ **Contractor** (Enter name and describe the language in the contract that safeguards PII.)

Specify. There are some providers and/or staff who are employed in a contractual basis. There are clauses in their contracts requiring compliance with the Privacy Act and Health Insurance Portability and Accountability Act (HIPAA) requirements to protect the confidentiality of personal information.

☒ **Other** (e.g., commercial providers, colleges).

Specify. The PII may be shared with a civilian sector health care provider qualified and licensed to interpret the data and only after the individual has signed an authorization for disclosure.

i. Do individuals have the opportunity to object to the collection of their PII?

☒ **Yes**

☐ **No**

(1) If "Yes," describe method by which individuals can object to the collection of PII.

Individuals review and sign a Department of Defense (DD) Form 2005, Privacy Act Statement - Health Care Records. This form is maintained in the individual's medical records.

(2) If "No," state the reason why individuals cannot object.

j. Do individuals have the opportunity to consent to the specific uses of their PII?

☒ **Yes**

☐ **No**

(1) If "Yes," describe the method by which individuals can give or withhold their consent.

Individuals review and sign a Department of Defense (DD) Form 2005, Privacy Act Statement - Health Care Records. This form is maintained in the individual's medical records.

(2) If "No," state the reason why individuals cannot give or withhold their consent.

k. What information is provided to an individual when asked to provide PII data? Indicate all that apply.

- | | |
|--|--|
| <input checked="" type="checkbox"/> Privacy Act Statement | <input type="checkbox"/> Privacy Advisory |
| <input type="checkbox"/> Other | <input type="checkbox"/> None |

Describe each applicable format.

A Department of Defense (DD) Form 2005, Privacy Act Statement - Health Care Records is provided to the patient at point of care. This form is maintained in the individual's medical records.

NOTE:

Sections 1 and 2 above are to be posted to the Component's Web site. Posting of these Sections indicates that the PIA has been reviewed to ensure that appropriate safeguards are in place to protect privacy.

A Component may restrict the publication of Sections 1 and/or 2 if they contain information that would reveal sensitive information or raise security concerns.